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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,311	04/11/2006	Nicola Anne Burgess	13001015PCTUS	5452

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EXAMINER	
GUSSOW, ANNE	
ART UNIT	PAPER NUMBER
1643	
MAIL DATE	DELIVERY MODE
03/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,311	BURGESS, NICOLA ANNE	
	Examiner	Art Unit	
	ANNE M. GUSSOW	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9,28 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,9,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence alignment*.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 23, 2007 has been entered.

2. Claims 7, 9, 28, and 29 are under examination.

3. The following Office Action contains NEW GROUNDS of Rejection.

Rejections Withdrawn

4. The rejection of claims 7, 9, 28, and 29 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting the phrase “a CDCP1 polypeptide comprising or consisting of the amino acid sequence of SEQ ID No. 1” is withdrawn in view of applicant’s amendment to the claims.

Rejections Maintained

5. The rejection of claims 7, 8, 28 and 29 under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained.

The response and declaration filed November 23, 2007 has been carefully considered but is deemed not to be persuasive. The response states that applicant submits a second Declaration executed by Dr. Mason, wherein data are presented demonstrating that binding and/or internalization of the antibody/polypeptide complex comprising unconjugated anti-CDCP1 antibody leads to cell death. As detailed in the Declaration and shown in Appendix B, a CDCP1-specific antibody specific for the extracellular domain of CDCP 1 mediates lysis of the human ovarian tumour cell line SKOV-3 in an antibody-dependent cellular cytotoxicity (ADCC) assay. Moreover, CDCP 1 antibody mediated lysis of SKOV-3 cells occurs in an antibody dose-dependent manner. The efficacy of the CDCP 1-specific antibody was also examined in a widely recognized animal model of experimental metastasis. This model system is explained in detail in the Declaration and experimental results pertaining to the system as adapted with respect to detectable cells that express CDCP1 and antibody mediated targeting of such cells are shown in Appendices C and D. In short, administration of the CDCP1 antibody to animals expressing detectable CDCP1 expressing cells leads to a dramatic reduction in detectable CDCP1 expressing cells at the site of metastasis as observed using in situ bioluminescent imaging technology. Manual quantitation of tumor metastases performed post mortem confirmed these results. In sum, the data presented in the Declaration demonstrate that a CDCP1-specific antibody mediates lysis of ovarian cancer cells in vitro and drastically decreases tumor growth and/or establishment in vivo of cells that express CDCP1. Based on these findings, a skilled practitioner would appreciate that an antibody specific for CDCP1 would target the

CDCP1 present on cancerous cells and be an effective therapeutic agent in vivo (see response page 4).

In response to this argument, the declaration of Dr. Mason provides evidence that a full length antibody of the IgG isotype is capable of inducing cell lysis in vitro when exposed to a crude separation of PBMCs (see figure 1 and declaration pages 2-3). The declaration also provides evidence that the full length antibody is capable of reducing tumor burden of a mouse model of melanoma in vivo. The claims are drawn to a method of treating ovarian cancer. It is not clear from the declaration or supporting documents filed with the declaration how the mouse model of melanoma relates to a method of treating ovarian cancer. The two cancers affect different cell types in different organ systems with different mechanisms.

Additionally, claim 28 recites that the antibody be an antibody fragment, it is not clear from the declaration if an antibody fragment would be effective in inducing the same response either in vitro or in vivo. One of ordinary skill in the art could contemplate the importance of the constant domain of the antibody in initiating the specific response to the antibody.

Therefore, after a fresh consideration of the claims and the evidence provided, the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 7, 9, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Schweifer, et al. (US 2002/0142003, published October 3, 2002).

The claims recite a method for the treatment of ovarian cancer comprising administering a therapeutically effective amount of an antibody which specifically interacts with a CDCP1 polypeptide comprising residues 30-667 of SEQ ID NO: 1, wherein the antibody is monoclonal, polyclonal, chimeric, humanized or bispecific, or is conjugated to a therapeutic moiety, detectable label, second antibody or a fragment thereof, an effector or reporter molecule, a cytotoxic agent or cytokine, wherein the therapeutic moiety is a toxin or a radionuclide.

Schweifer, et al. teach monoclonal antibodies that bind to B345 for therapeutic and diagnostic applications in cancer. Schweifer, et al. teach that the antibodies may be humanized, chimeric, labeled with cytotoxic agents or radionuclides (see paragraphs 52-55). The sequence of B345 is 99.8% identical to the sequence of SEQ ID No.1 (see sequence alignment). Since the only active step of the method is the administration of an antibody which binds to a polypeptide comprising residues 30-667 of SEQ ID No. 1, and the open comprising language reads on an antibody which would bind to SEQ ID

No. 1, an antibody which binds to B345 would also bind to CDCP1 of SEQ ID No. 1 because there are only 2 amino acids different between the two sequences. Therefore, the antibody of Schweifer, et al. administered to treat cancer would anticipate the instant claims.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

February 11, 2008

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643